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TITLE: A Pilot Trial to Assess Implantable Myoelectric Sensors (IMES) to Improve Prosthetic Function for Transhumeral Amputees with Targeted Muscle Reinnervation

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CONTRACTING ORGANIZATION: Henry M. Jackson Foundation for Advancement of Military Medicine
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14. ABSTRACT
The overall project goal is to investigate the functional performance of transhumeral amputees who have received targeted muscle reinnervation with EMG signals measured intramuscularly using a fully wireless implant. During the first year we successfully signed subcontracts with Cirtec Medical and Med Institute, the two companies that are assisting with obtaining the IDE from the FDA. We also successfully completed a first draft of the IRB protocol.

15. SUBJECT TERMS
Recruitment, infrastructure, patient identification

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1. Introduction

The inadequacies of current prosthetic technologies severely limit rehabilitative options for upper limb amputees and contribute to the disability caused by upper limb loss. TMR presents new possibilities for control of upper limb prostheses, and, building on this success, our team has developed innovative technologies to address key remaining challenges in the design and control of advanced prosthetic systems. The overall objective of this grant is to improve functional independence for individuals with transhumeral amputees, who have had TMR using implantable MyoNodes. Our hypothesis is that chronic implants within reinnervated muscle will provide stable EMG recordings that will allow intuitive, simultaneous control of 3 DOF prosthesis system. Furthermore, we hypothesize that this technology will result in significant functional improvements for users as measured through the ACMC, SHAP, clothespin relocation, Jebsen Hand task, and box-and-block tasks.

Aim 1: Obtain a feasibility study investigational device exemption for the MyoNode system.
Extensive preliminary work has already been conducted to develop and test the MyoNode prototype, with demonstration of successful wirelessly powered and telemetered data from a tissue depth of 10 cm in an animal model. All design files have been transferred to Cirtec Medical Systems to create final form factor devices under GMP and are working with Med Institute Inc., to obtain a feasibility Investigational Device Exemption (IDE) from the FDA. These activities are being coordinated by ZIPH Labs. The engineering, fabrication, and regulatory team has extensive experience in developing implantable medical devices, and preliminary engagements with the FDA have indicated that an Early Feasibility Study (EFS) IDE will be received within 18 months.

Aim 2: Assess the accuracy with which transhumeral amputees can control isolated and simultaneous movements of a three DOF myoelectric prosthesis utilizing the MyoNode system after successful TMR surgery.

TMR has proven very useful for enhancing prosthesis control. However, to date, subjects have been limited to using surface EMG signals to control a prosthesis. Surface EMG is often corrupted by muscle cross-talk and instability in the skin-electrode interface necessitates frequent recalibration of controllers. We will recruit three individuals with transhumeral amputations and who have had TMR surgery. As our basic control platform, we will use natively innervated biceps and triceps to provide direct proportional control of the elbow, and we will try both direct control and pattern recognition of EMG from reinnervated muscles to control the wrist and hand. Subjects will complete 3-DOF Fitt's Law virtual testing to measure throughput of discrete and simultaneous measurements. We will also measure subjects' control of a physical prosthesis as they complete movements which require discrete and simultaneous movements. A commercially available prosthesis with an elbow, a wrist rotator, and a hand will be used in conjunction with commercially available pattern recognition software (Coapt LLC). The only variable will be the input signals; allowing us to compare performance using IM and/or surface EMG signals, and with data from other transhumeral TMR subjects using the pattern recognition controller with surface EMG (W81XWH 12-02-0072).

Aim 3: Determine the ability of transhumeral amputees to successfully perform functional activities using a three DOF myoelectric prosthesis control by the MyoNode system and TMR.

We hypothesize that the MyoNode implant system will improve control of the prosthesis, and that this will subsequently improve functional activities. We will measure functional performance prior to implantation and during training with the MyoNode system, using the SHAP, ACMC, a clothespin relocation task, the Jebsen

task, and the box and blocks task. We will also provide the subjects with a questionnaire for subjective feedback at the end of the study.

In our original project plan, The MyoNode System was planned to be ready for implantation by March 2016, allowing for adequate time for FDA approval and to complete the three aims within the 4 year trial period. However, delays in project start date due to the contracting process has delayed our plan. Fortunately, we were able to complete significant technology development during the contracting delays as part of other ongoing work so that the overall project schedule impact should be minimized.

2. Body

During the first year of the project, we completed final development and testing of the MyoNode external powering coil. Prior work has resulted in a completed and fully functional implant meeting the specifications required for this project. The requirements for the coil are that it be capable of powering 8 MyoNodes simultaneously with a form factor that can be incorporated into the socket of a transfemoral prosthesis.

We created a finite element model dimensioned to the 50% male humeral section of an arm (Fig 1). Next, we simulated a set of coil parameters and receiving power antennas that met the project specifications to verify that the power adequate power transmission could be achieved.

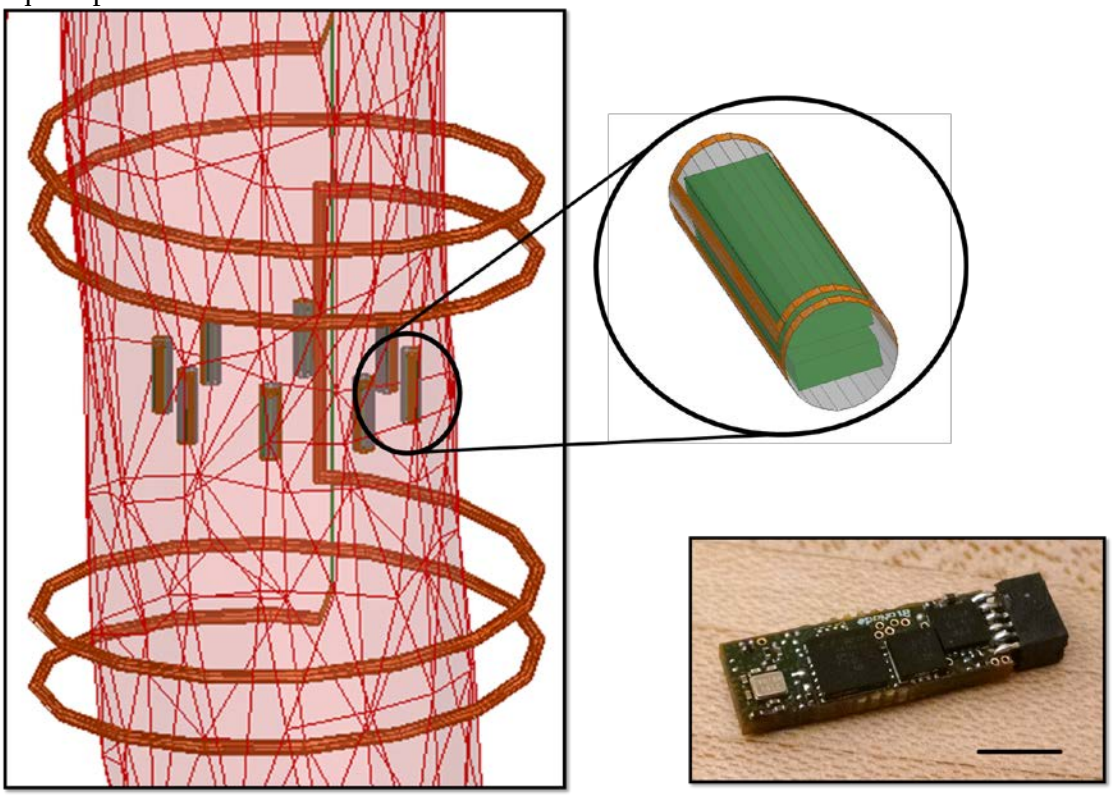

Figure 1: The finite element model of the humeral section of arm, displaying arbitrarily placed MyoNode sensors. Shown in the bottom right is a MyNode chip with a scale indicator of 5 mm.

Based on the results of the simulation, we determined that an anti-Helmholtz coil design could be used to power the device. A physically realizable antenna could be constructed by printing a coil on a flexible substrate and placed inside of the Myonode cylindrical package (Fig 2).

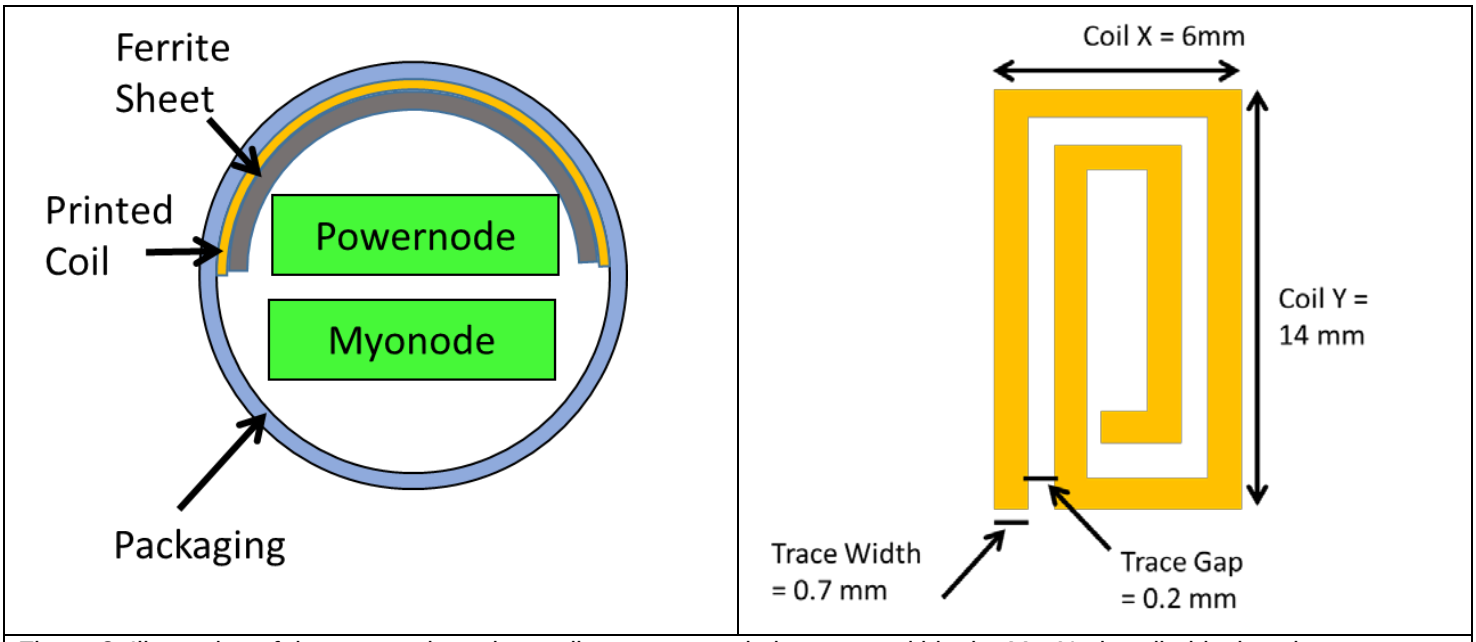

Figure 2: Illustration of the powered receiver coil geometry and placement within the MyoNode cylindrical package.

In the second project quarter, we will construct a physical model of the system and demonstrate full system functionality on a physical rather than simulation model.

We next completed a modelling and simulation study to demonstrate the technical feasibility of the fully wirelessly powered system in the size and shape required to complete this study (Figures 3 and 4).

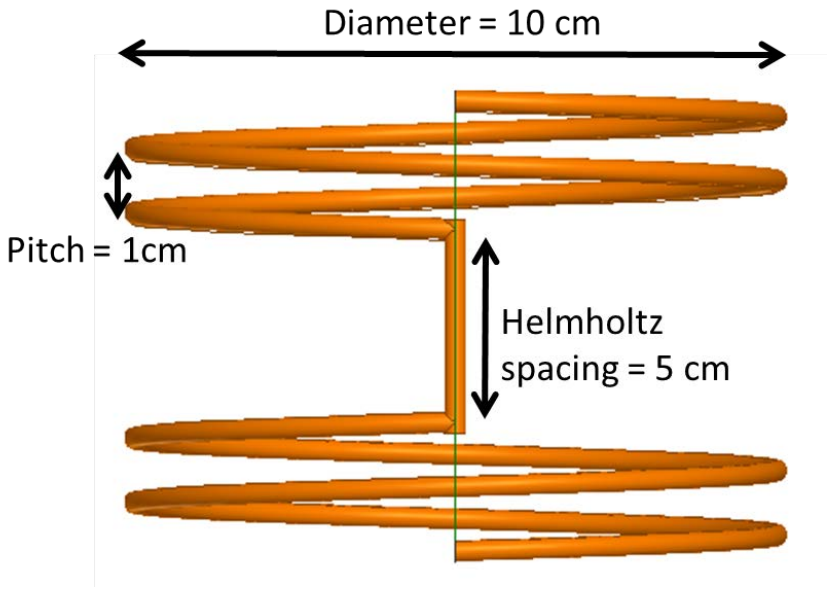

Figure 3: Anti-Helmholtz Coil for wireless powering.

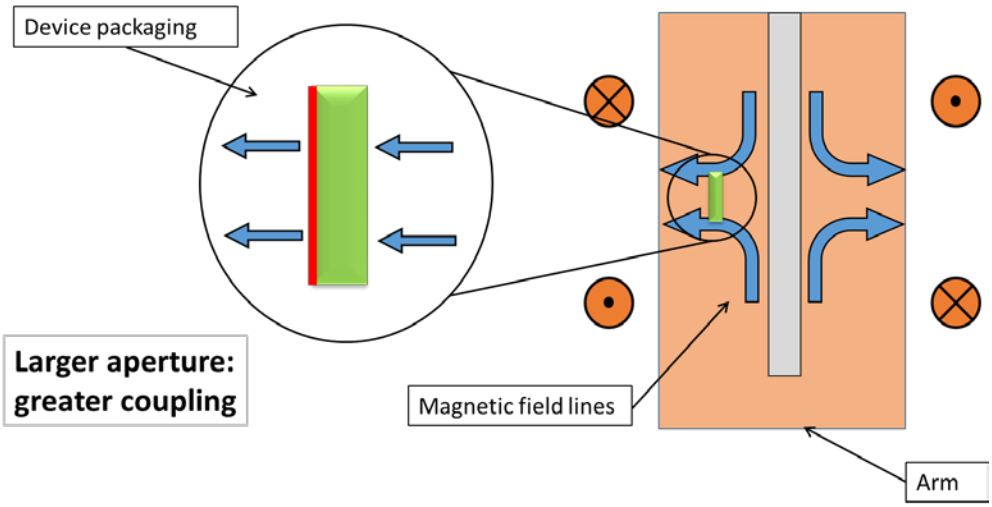

Figure 4: Illustration showing magnetic field lines relative to implant packaging.

The device was tested using a modified MyoNode implant. This implant had the wireless powering system active, but did not include a data acquisition and transmission system. Rather, the transmitted power was used to light a light-emitting-diode (LED) that consumed the same amount of power that was budgeted for each MyoNode. When tested, we verified power was successfully delivered 8 MyoNode devices; however, there were two limitations 1) the powering coil was constructed from stiff wire, which would make it challenging embed within a socket and 2) the power transmission was sensitive to the orientation of the implant packing. This is primarily caused by the geometry of magnetic field lines relative to the power harvesting coil. Consequently, a second model was constructed to address these concerns.

The second physical model was constructed using amore malleable powering coil and was wrapped around the exterior of a diagnostic socket that was previously used as part of a fitting for a transhumeral amputee who had received targeted muscle reinnevation. The socket was filled with a ground-beef as a crude magnetic model what might be expected from tissue (Figure 5).

Figure 5: A diagnostic socket from a transhumeral amputee filled with ground beef and wrapped with the power telemetry coil.

We also wished to power a fully functioning MyoNode device that included data acquisition and telemetry. Thus we used a device that was slightly larger than the device which will be used in the final form factor for this project, but restricted the coil to cylindrical form factor (Figure 6). The miniaturization of the components is in our scope of work and will be commencing next quarter. The device was placed in different locations with the cavity and wireless powering and transmission were verified using a base-bastion to receive the data, even when powered with a lower power source than was provided in the device specifications.

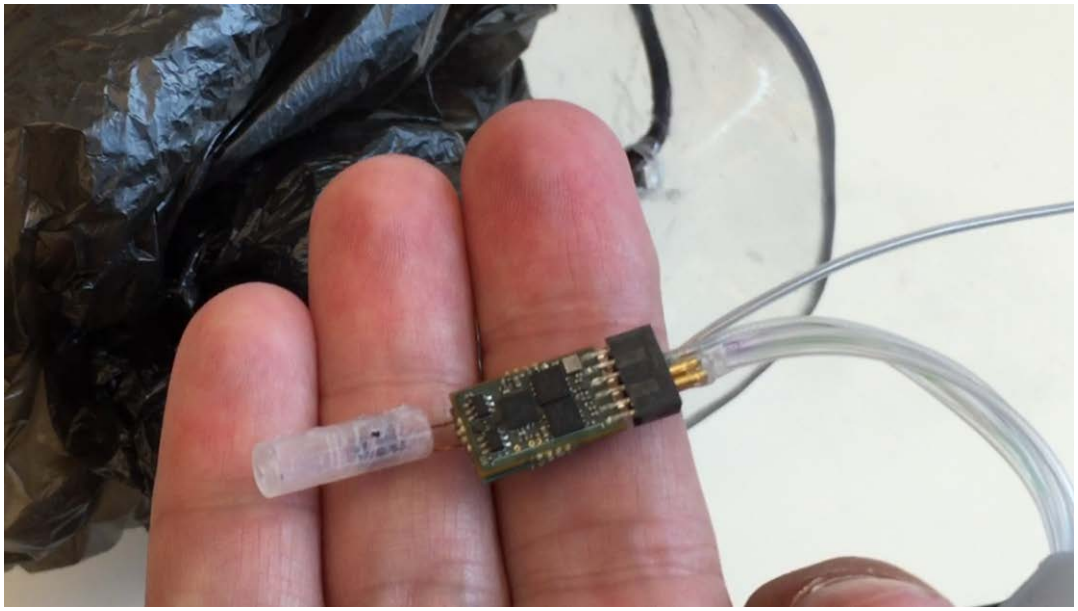

Figure 6: Fully functioning device being powered with a coil geometry that fits within the project specifications.

Based on these physical model testing, we are confident that the MyoNode device is operating as expected and will meet the needs of this project.

Lastly, we have completed the technical developments required to successfully create the full MyoNode system and engaged our regulatory (Med Institute) and manufacturing partners (Cirtec Medical). The design is now in the process of being put under the design controls required to successfully acquire an Investigational Device Exemption. Project and engineering documents have now been created under the design control process for: the Communication Plan, Quality Plan, Risk Management Plan, User Needs Assessment, Development Plan, Engineering Specifications, Applicable Standards, Hazard Analysis and Design Verification Plan. Progression through these documents has led to a decision regarding the final prototype design, which has now been fabricated. This design package has been delivered to our manufacturing partners who are performing a Gap analysis to see what, if any, additional design controls need to be met to meet our user design needs document (Figure 7).

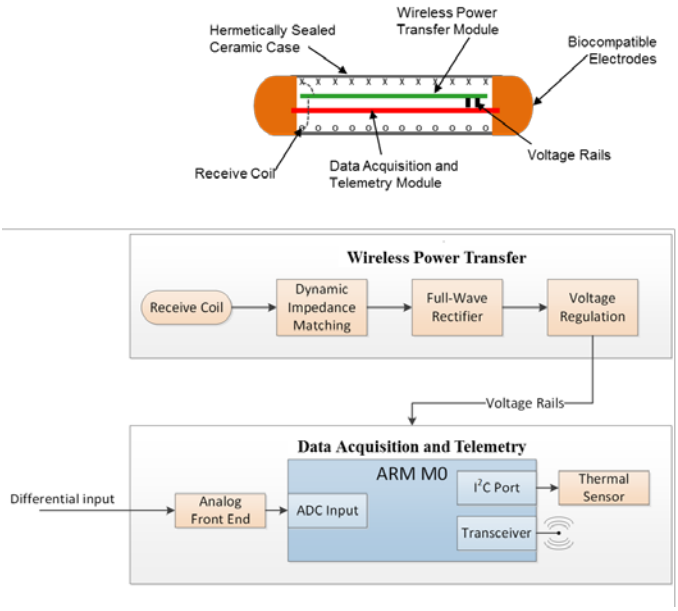

Fig 7: Block diagram of the implant portion of the MyoNode System

Briefly, the design package is comprised of two components. The first component is the implant which will be encased in a hermetically sealed and biocompatible package (Fig 7). Several refined prototypes have been fabricated and we are confident in both the powering technology and the data acquisition and telemetry aspects. The second component is the base-station which attaches to an external powering coil (Fig 8). Again, we have fabricated several prototypes and verified proper functioning. We are now evaluating how much the physical size of the base-station may be optimized to allow for it to be easier to incorporate into the patient socket.

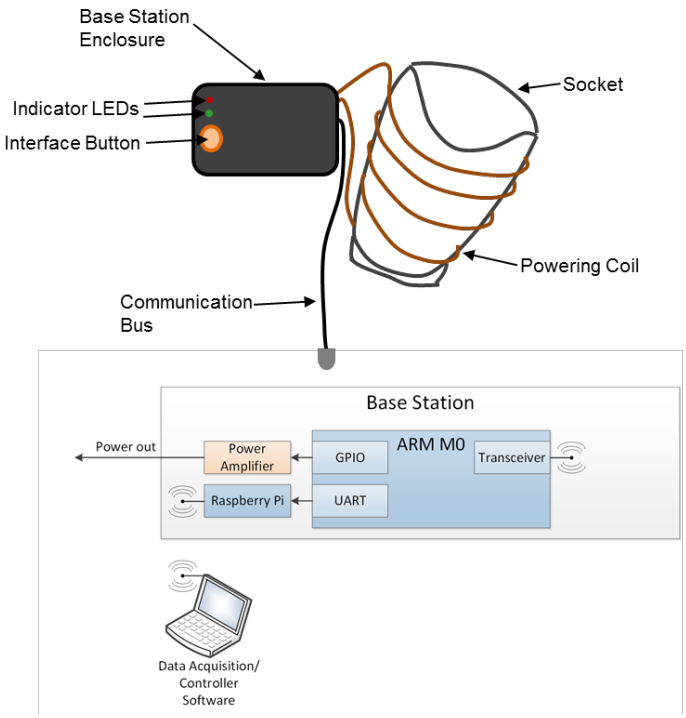

Fig 8: Block diagram of the base-station component of the MyoNode system.

3. Key Research Accomplishments

***** Technical Project Kickoff Meeting between Med Institute, Cirtec Medical, RIC, and Purdue University
* Design package creation of final physical prototype of the Myonode implant and interim base-station design.
* Creation of design control documents in draft form.

4. Reportable Outcomes and Conclusions

For the first year, there were no reportable outcomes; however, we have made excellent progress toward achieving our overall project goals.

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A Pilot Trial to Assess Implantable MyoNodes to Improve Prosthetic Function for Transhumeral Amputees after Targeted Muscle Reinnervation

W81XWH-16-2-0009

PI: Paul F. Pasquina, MD **Org:** Henry M. Jackson Foundation

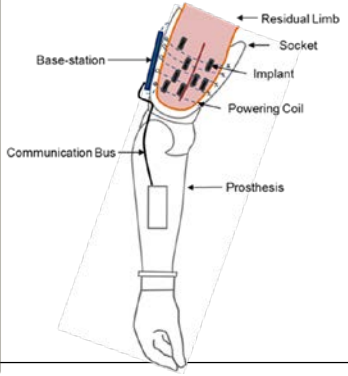
Award Amount $2,622,160

Study Purpose / Deliverables

Current prosthetic technologies severely limit rehabilitative options for upper limb amputees and contribute to the disability caused by upper limb loss. Targeted muscle reinnervation (TMR) presents new possibilities and the overall objective of this grant is to improve functional independence for individuals with transhumeral amputees, who have had TMR using implantable MyoNodes.

Study Aims

Aim 1: Investigational device exemption for the MyoNode system.
Aim 2: Assess the accuracy and control of a 3 DOF myoelectric prosthesis utilizing the MyoNode system after TMR surgery.
Aim 3: Determine the ability of transhumeral amputees to successfully perform functional activities using a three DOF myoelectric prosthesis control by the MyoNode system and TMR.



Accomplishments: Created design control documents for the MyoNode system and completed drafts of communication plan, user design needs, product specification, communication plan, risk management plan, and hazard traceability matrix. Also completed design package to transition to manufacturing partner for documentation gap analysis.

Timeline and Cost

Activities FY	16	17	18-20
Execute subaward agreements			
Complete development work			
Obtain IDE from the FDA			
Evaluate technology and publish findings			
Estimated Budget ($K)	**$2100**	**$250**	**$250**

Updated: 15 May 2017

Goals/Milestones

FY16 Goals
- ☑ Execute subaward agreements between institutions
- ☑ Technical Demonstration of MyoNode Technology

FY17 Goals
- ☐ Complete MyoNodes developmental work
- ☐ Obtain investigational device exemption (IDE) from the FDA

FY18-20 Goals
- ☐ Obtain institutional review board (IRB) approval
- ☐ Assess the accuracy of the MyoNodes system after TMR
- ☐ Perform functional test with the MyoNodes system
- ☐ Complete the final study report and publish findings

Budget Expenditure to Date: $2,028,196
Projected Expenditure: $2,622,160